

AWARD NUMBER: W81XWH-13-2-0014

TITLE: Joint Global War on Terror (GWOT) Vascular Injury Study 2

PRINCIPAL INVESTIGATOR: MAJ Zachary Arthurs, MD

CONTRACTING ORGANIZATION: The Geneva Foundation
Tacoma, WA 98402

REPORT DATE: February 2015

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE February 2015		2. REPORT TYPE Annual Report		3. DATES COVERED 1 Feb 2014 - 31 Jan 2015	
4. TITLE AND SUBTITLE Joint Global War on Terror (GWOT) Vascular Injury Study 2				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-13-2-0014	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) MAJ Zachary Arthurs - zachary.m.arthurs.mil@mail.mil E-Mail:				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The Geneva Foundation 917 Pacific Avenue Suite 600 Tacoma, WA 98402				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The objective of the proposed study is to initiate a large scale investigation of patient based outcomes following extremity vascular injury in the wars in Afghanistan and Iraq. This study proposes a link acute injury and clinical management information from the Joint Theater Trauma Registry (JTTR) to authentic patient-based outcomes years following injury. In this effort, the study aims to provide novel information on amputation and return to duty rates as well as to characterize the relationship between eventual quality of limb and psychological recovery or well-being.					
15. SUBJECT TERMS Extremity vascular injury, extremity, vascular injury, vascular trauma, vascular injury management, survey, OIF, OEF, Iraq, Afghanistan, deployment, training					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT U	18. NUMBER OF PAGES 8	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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1. INTRODUCTION:

The objective of this study is to initiate a large scale investigation of patient based outcomes following extremity vascular injury in the wars in Afghanistan and Iraq. This study links acute injury and clinical management information from the Joint Theater Trauma Registry (JTTR) to authentic patient-based outcomes years following injury. In this effort, the study aims to provide novel information on amputation and return to duty rates as well as to characterize the relationship between eventual quality of limb and psychological recovery or well-being. Finally, this program aims to characterize and compare the physical and emotional burden in large cohorts of US service personnel having had successful limb salvage or amputation in the years following extremity vascular injury. An updated vascular study is needed to evaluate long-term outcomes and lifelong follow-up of the injured Service Member with vascular injury.

2. KEYWORDS:

Extremity vascular injury, extremity, vascular injury, vascular trauma, vascular injury management, survey, OIF, OEF, Iraq, Afghanistan, Iraq, deployment, training

3. ACCOMPLISHMENTS:

What were the major goals of the project?

- **Study Phase I (Acute and Mid-Term Data Collection):**
 - Several databases, including the JTTR, WISPR, PASBA, JPTA, AHLTA, DEERS, etc., will be searched to identify Service Members who incurred vascular injury in theater.
 - To augment data on acute injury characteristics and management strategies, a retrospective review of the medical records of those in the cohort will be performed.
- **Study Phase II (Patient Based Outcomes):**
 - Service Members identified via the database established in Phase I will be contacted to obtain status information to include the most recent date of vascular follow-up.
- **Study Phase III (Analysis):**
 - Information from Phase I and Phase II will be analyzed to provide comprehensive descriptive information on the patient cohort pertaining to demographics, injury information and management strategies.

What was accomplished under these goals?

The project was awarded in February 2013. Study Phase I of the project is underway and we have developed the surveillance program design and identified Service Members who incurred vascular injury. To date, four research nurse coordinators, one research fellow, one technical writer, one program manager, and one biostatistician have been hired in support of the award. Current study staff consists of a program manager and four research nurses. The GWOT 2 Wartime Vascular Injury Study is an ongoing effort; therefore, the number injured continues to grow contingent upon additional potential subjects that are added to the database from yearly queries derived from the Department of Defense Trauma Registry (DoDTR). Currently, 3,560 potential subjects have been identified. The Principal investigator, Col Todd Rasmussen, changed duty stations and he is now at Fort Detrick in Combat Casualty Care.

MAJ Zachary Arthurs was selected to be the incoming PI of this effort by Col Rasmussen and has taken leadership of the protocol. HRPO approval was obtained September 9, 2014. Research staff has attempted to contact approximately 200 patients to obtain follow-up data and complete surveys; 33 of these individuals have completed the online survey/data collection.

What opportunities for training and professional development has the project provided?

Nothing to Report

How were the results disseminated to communities of interest?

We aimed at disseminating and promoting the GWOT 2 Wartime Vascular Injury Study to the research community through national civilian and military academic conferences/or meetings. Details are included in Section 6 of report. Additionally, once we complete manuscripts, these will be submitted to peer-reviewed journals for publishing.

What do you plan to do during the next reporting period to accomplish the goals?

Future plans include ongoing continuous review of Wartime Vascular Injury Database to amplify recruitment and return of surveys for data collection and hire additional staff to support project. The Data Sharing Agreement with the Defense Health Agency for access to medical records for review is pending, with a goal for completion by December 2015. Additionally, an agreement between the Veterans Affairs Health System and the ISR for Future plans to amplify recruitment and return of surveys for data collection is being explored. Research staff has a goal of 400 contact attempts for calendar year 2015.

4. IMPACT:**What was the impact on the development of the principal discipline(s) of the project?**

Vascular injury represents a common cause of morbidity and mortality in, not only wartime, but also the civilian trauma sector in the US. Historically, advances in the management of civilian disease and injury have resulted from wartime experience in the areas of burn care, resuscitation, infectious disease and vascular surgery. What is learned from the mid and long-term follow up provided by this study will undoubtedly impact the management of age-related vascular disease in the United States. Additionally, the management of vascular injury in the civilian setting stands to benefit from the activities of this study. Given the minimal published data on host national vascular injuries, any information in this arena would be of potential benefit to developing proven management strategies. Lastly, understanding vascular injury including limb ischemia and reperfusion is relevant to other vascular distributions including the coronary and cerebro-vascular circulations which are also prone to ischemic insult.

For the first time, this study proposes a mixed methods approach to link data from the time of injury, the subsequent medical record, and real time patient-based outcomes assessment years after injury. In this context, the proposed study encompasses the entire timeline from point of battlefield injury to eventual perceived physical and psychological recovery. Findings from this study stand to characterize the physical and psychological impact of extremity vascular injury and guide military providers, patients and their families as they cope with recovery from extremity injury. Finally, in characterizing the relationship between the SMFSA and the SF-36 surveys, this study promises to provide novel insight in to a long suspected, but never quantified, relationship between quality of limb and quality of life; a finding that would impact the management of military and civilian extremity injury worldwide.

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS:**Changes in approach and reasons for change**

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to Report

Changes that had a significant impact on expenditures

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

To date 29 amendments and 31 protocols versions have been submitted and approved by Brooke Army Medical Center IRB. Most recently amendment #28 was submitted adding and removing personnel due to staffing changes and addition of a HIPAA Waiver to allow for the use of extracted medical record data for those subjects whom the RNCs are unable to contact. This amendment was approved on 14 August 2014. The protocol was approved by the MRMC HRPO office in September 2014.

6. PRODUCTS:

Publications, conference papers, and presentations

- Mid-term, amputation free survival and patient based outcomes following wartime vascular injury-The American Association for the Surgery of Trauma 18-21 September 2014, podium presentation
- REBOA-Clinical Use and Update for Vascular Wartime Injuries-Trauma Rounds and Symposium at the Aberdeen Royal Infirmary, 7 November 2013
- Use of the Short Musculoskeletal Function Assessment for Assessing Limb-Specific Outcomes Following Extremity Vascular Injuries-Society for Military Vascular Surgery and Peripheral Vascular Surgery Society, 30 January 2014, podium presentation
- Mental health co-morbidities of service members with extremity vascular injuries acquired in Iraq and Afghanistan, Society for Trauma Nurse, 2-4 April 2014, poster presentation
- Vascular discharge education and follow-up care subsequent to wartime vascular trauma; Presented in San Antonio, TX, May 2014

Journal publications.

Nothing to Report

Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers, and presentations.

Nothing to Report

Website(s) or other Internet site(s)

Nothing to Report

Inventions, patent applications, and/or licenses

Nothing to Report

Other Products

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Col Todd E. Rasmussen, MD, FACS
Project Role:	PI
Nearest person month worked:	2

Contribution to Project:	Col Todd E. Rasmussen is the former PI of the award
Name:	MAJ Zachary M. Arthurs, MD
Project Role:	PI
Nearest person month worked:	2
Contribution to Project:	MAJ Zachary M. Arthurs is the current PI of the award
Name:	Thomas Evans
Project Role:	Research Nurse
Nearest person month worked:	12
Contribution to Project:	Mr. Evans assisted in developing the surveillance program design and identified Service Members who incurred vascular injury
Name:	Joe Holguin
Project Role:	Research Nurse Coordinator
Nearest person month worked:	11
Contribution to Project:	Mr. Holguin assisted in developing the surveillance program design and identified Service Members who incurred vascular injury
Name:	Shawn Dalle Lucca
Project Role:	Technical Writer
Nearest person month worked:	9
Contribution to Project:	Ms. Dalle Lucca provided technical writing expertise to GWOT Wartime Vascular Injury staff
Name:	Kira Long, MD
Project Role:	Research Fellow
Nearest person month worked:	8
Contribution to Project:	Dr. Kira Long assisted in developing the surveillance program design and identified Service Members who incurred vascular injury
Name:	Andrea Russell
Project Role:	Research Nurse
Nearest person month worked:	12
Contribution to Project:	Ms. Andrea Russell assisted in developing the surveillance program design and identified Service Members who incurred vascular injury
Funding Support:	USAISR, Research Directorate
Name:	Lee Ann Zarzabal
Project Role:	Biostatistician
Nearest person month worked:	1
Contribution to Project:	Ms. Zarzabal provided biostatistician and data analysis expertise to GWOT Wartime Vascular Injury staff
Name:	Diane Miller
Project Role:	Research Nurse
Nearest person month worked:	12

Contribution to Project:	Diane Miller assisted in developing the surveillance program design and identified Service Members who incurred vascular injury
Name:	Irma McNamee
Project Role:	Research Nurse
Nearest person month worked:	12
Contribution to Project:	Irma McNamee assisted in developing the surveillance program design and identified Service Members who incurred vascular injury
Name:	Julie Cutright
Project Role:	Research Nurse Coordinator
Nearest person month worked:	3
Contribution to Project:	Recently joined the program to help contact identified Service Members
Name:	Matt Markell
Project Role:	Program Manager
Nearest person month worked:	6
Contribution to Project:	Provides high-level, research project management

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

The Principal investigator, Col Todd Rasmussen, changed duty stations and is now at Fort Detrick in Combat Casualty Care. MAJ Zachary Arthurs was selected to be the incoming PI of this effort by Col Rasmussen and has taken leadership of the protocol and award. Additionally, Maj Brandon Propper is assisting MAJ Zachary Arthurs to lead the program. Both are vascular surgeons at SAMMC. Geneva sent a request for PI change from Col Todd Rasmussen to MAJ Zachary Arthurs to sponsor on 20 Feb 2014. Dr. Rose Ramos and COL Lorne Blackburn are no longer working in support of this award. MAJ Zachary Arthurs assumed the role of PI in August 2014, after sponsor approval.

What other organizations were involved as partners?

Organization Name: USAF 59MDW/ST Chief Scientist's Office
Location of Organization: 2200 Bergquist Dr. Ste 1.
 JBSA Lackland AFB, TX 78236

Partner's contribution to the project

- Facilities-project staff use the partner's facilities for project activities

Organization Name: United States Institute of Surgical Research
Location of Organization: 3698 Chambers Pass
 JBSA Fort Sam Houston, Tx 78234-6315

Partner's contribution to the project

- Facilities-project staff use the partner's facilities for project activities
- Collaboration-Support for Ms. Andrea Russell's time in support of award.